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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,322	04/23/2001	Long Y. Chiang	06897-006001	4062
26161	7590	03/03/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER

1615

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,322

Applicant(s)

CHIANG, LONG Y.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and remarks both dated 12-29-03 is acknowledged.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

In response to applicant's arguments the outstanding rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Claim Rejections - 35 USC § 112

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the growth of tumor cells in a tumor site by administering sulfobutylated hexadecaniline, does not reasonably provide enablement for all the oligoaniline derivatives that are within the scope of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability of the art, and the working examples. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

All rejected claims are drawn to the methods of inhibiting the growth of tumor cells with the administration of the instant composition. The nature of the invention is extremely complex

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in that it encompasses a number of tumors or metastasis conditions and inhibiting the growth of the tumors, and further with a vast number of oligoaniline derivatives. The complex nature of the claims is exacerbated by the breadth of the claims. The claim encompasses a number of oligoanilines as described in claim 1. In particular, variable W could be as simple as hydrogen, to ethers, alkyl ethers, amino containing groups, thioalkyl ethers, urethane, alkyl amide anhydride, carbonate, ester, complex esters, with the number of groups being any where between 1-2000 for alkyl or 1-100 for other groups. Similarly, the variable X ranges can be hydrogen or O-Z, S-Z or -NH-Z- where Z is E-D, E being alkyl or aryl-alkyl and D being a OH, SH or as complex as a phosphate or glycosidic group. Thus, the instant oligoanilines encompass a vast number of compounds.

The state of the art does not recognize the administration of compositions that encompasses the entire range of compounds to inhibit the growth of all types of tumors using a single compound. Instant specification does not describe or teach how to prepare the compounds encompassed by instant oligoanilines and their use to inhibit the growth of a tumor cell at a tumor site. Instant specification only describes in vitro inhibition of murine sarcoma cells using sulfobutylated hexadecaniline as an example representing the entire range of compounds claimed. However, applicants have provided no basis to extrapolate the efficacy of a sulfonylated hexadecaniline to the myriad of possible compounds claimed, in inhibiting the tumor growth as claimed. The claimed formula of oligoaniline as explained results in compounds with different structural and hence functional properties, depending on the variables substituted for A, W, X and K. For instance, the simplest compound possible is aminobenzene or aniline because of the fact that m and n are integers that could have a value of 1. However, aminobenzene has a

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completely different structure and possess a different function from an oligoaniline compound containing glycoside group (for variable D) or a urethane substitution (for W). Applicants have explained the mechanism by which claimed oligoaniline exert the anti-tumor effect on pages 6-7 of the application. Applicants state that when photo-excited, oligoanilines convert molecular oxygen into singlet oxygen and related free radicals, such as superoxide free radicals and hydroxyl radicals. The free radicals subsequently cause damage to surrounding tumor cells and inhibit the growth of the tumor cells (i.e., reducing the number and size of the tumor cells). However, applicants have not described if all of the different types of oligoanilines that result from the instant formula I would possess the ability to get photo-excited and convert molecular O₂ to singlet oxygen and related free radicals and that all the resulting compounds are effective in inhibiting the tumor cell growth. The instant example only provides a 40% reduction in the growth of tumor cells, which is not a complete inhibition. Taken together with innumerable tumor types and stages of tumors, the specification lacks guidance and also provides no evidence that entire possible range of compounds are effective for inhibiting the growth all types of tumor cells and whether the administration of the instant composition is effective in inhibiting the growth of a tumor cell at any stage of the tumor i.e., early or late stages. The lack of significant guidance from the specification or prior art makes practicing the claimed invention unpredictable in terms of choosing the appropriate oligoaniline compound out of the claimed range of compounds and the inhibition of the tumor progression. Therefore, the practitioner would turn to trial and error experimentation to make/use the instant compositions with a different oligoaniline compound and test its efficacy for inhibiting the growth different types of tumor cells, at

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different stages of growth cycle, without guidance from the specification or the prior art.

Therefore, undue experimentation becomes the burden of the practitioner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 507 488 (EP).

EP teaches novel aniline derivatives and pharmaceutical compositions comprising aniline derivatives and a pharmaceutically acceptable carrier (see abstract and pages 1-3). The aniline derivative of EP (formula I, page 1) reads on the instant claimed oligoaniline for the following reasons:

EP teaches variables R1, R2, R3, R5 and R6 can be H. Instant variables K, A and X can be H. With respect to claimed variable W, instant claim states that W can be CH₂-B, where B can be an aryl group. Given R6 of EP is H atom, then the attachment on N of EP will be – (CH₂)_n-aryl, thus reading on the instant compound. EP teaches pharmaceutical formulations containing appropriate carriers (page 7). Instant limitation “for inhibiting...” denotes intended use and carries no patentable weight. Therefore, EP anticipates instant claim 18.

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Claims 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,330,542 to Descamps et al (Descamps).

Descamps teaches sulfonylaniline derivatives for treating angina pectoris. The aniline compounds of Descamps described in formula I (col. 1-2) read on aniline compound of instant claims because claims 19-20 state that $A=Z$, which in turn is represented by E-D. Further claims state that $E=R$ (alkyl) and $D=SO_3H$. Accordingly, $A=Z=E-D=CH_2-SO_3H$. Descamps teaches a sulfonyl derivative attached to N and thus reads on the instant claimed compound. Further, Descamps teaches pharmaceutical compositions containing sulfonyl anilines and carriers containing the same. Instant limitation "for inhibiting..." denotes intended use and carries no patentable weight. Therefore, Descamps anticipate instant claims 18-21.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
February 27, 2004



Gollamudi S. Kishore, PhD
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